Medtronic News

Valiant 'Mona LSA' Stent Graft System from Medtronic Demonstrates Proof of Concept in Early Feasibility Study

Thomson Reuters ONE via COMTEX) --Presented at VEITH, Acute Results from Initial Trial of New Medical Technology Show Promise for Endovascular Approach to Thoracic Aortic Aneurysms Involving Left Subclavian Artery

NEW YORK -- Nov. 20, 2013 -- The first device of its kind to undergo clinical evaluation in the United States, the Valiant "Mona LSA" branch thoracic stent graft system from Medtronic, Inc. (NYSE: MDT) has demonstrated proof of concept in a first-in-human study being conducted under the U.S. Food and Drug Administration (FDA)'s "Innovation Pathway" early feasibility pilot program, according to data presented today at the 2013 VEITHsymposium(TM).

The early feasibility study was approved by the FDA under an investigational device exemption and enrolled seven patients from the United States to demonstrate proof of principle and initial clinical safety. Acute procedure results from all seven patients revealed 100 percent technical success and 100 percent patency in both main and branch stent graft. There were no type I or III endoleaks.

"The initial results of this early feasibility study are extremely encouraging," said Frank Arko, MD, a vascular surgeon at Carolinas HealthCare System's Sanger Heart & Vascular Institute in Charlotte, N.C., and one of the study's two U.S. investigators.

"This new technology could potentially minimize the need for invasive surgery and extend the benefits of endovascular repair without additional surgery to more patients with thoracic aortic aneurysms."

The Valiant Mona LSA system is designed to enable endovascular repair of thoracic aortic aneurysms encroaching on the left subclavian artery (LSA) by excluding the aneurysm from blood flow while maintaining perfusion of the LSA. Based on the market-leading Valiant Captivia thoracic stent graft, the investigational system features a branch cuff that accommodates the LSA branch graft. Its unique design eliminates the routine requirement for surgical LSA bypass, which proves necessary following about 40 percent of thoracic aortic aneurysm cases where coverage of the LSA is required to achieve a seal zone with the stent graft.

The Valiant Mona LSA system was the first of nine devices selected for evaluation as part of the FDA's Innovation Pathway, a new pilot program intended to encourage early-stage clinical investigation of new medical devices in the United States. More information about the program can be found on the FDA website.

"Thoracic aortic aneurysms involving branch vessels such as the LSA can be particularly challenging to treat," said Eric Roselli, MD, a cardiothoracic surgeon at the Cleveland Clinic and the study's national primary investigator. "The Valiant Mona LSA system could help address an unmet need in the treatment of thoracic aortic aneurysms. This is clearly reflected in the FDA's decision to help advance the development of this new therapy."

In collaboration with leading clinicians, researchers and scientists, Medtronic offers the broadest range of innovative medical technology for the interventional and surgical treatment of cardiovascular disease and cardiac arrhythmias. The company strives to offer products and services that deliver clinical and economic value to healthcare consumers and providers worldwide.

ABOUT MEDTRONIC

Medtronic, Inc. (www.medtronic.com), headquartered in Minneapolis, is the global leader in medical technology -- alleviating pain, restoring health and extending life for millions of people around the world.

Any forward-looking statements are subject to risks and uncertainties such as those described in Medtronic's periodic reports on file with the Securities and Exchange Commission. Actual results may differ materially from anticipated results.

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